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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,792	09/23/2003	Bernard E. Cabana	4354-110	4322

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1629	

MAIL DATE	DELIVERY MODE
06/28/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/668,792	CABANA ET AL.	
	Examiner	Art Unit	
	PHYLLIS SPIVACK	1629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,44-49,52-57 and 59-61* is/are pending in the application.

4a) Of the above claim(s) *44-48* is/are withdrawn from consideration.

5)☒ Claim(s) *1,2,4,5 and 52* is/are allowed.

6)☒ Claim(s) *49,53-57 and 59-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Response filed April 18, 2011 is acknowledged. Claim 3 is canceled. Claims 1, 2, 4, 5, 44-49, 52-57 and 59-61 are pending. Claims 44-48 remain withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions. **All of the claims that are presently under consideration are drawn to compositions.**

Claims 1-5, 49, 52-57 and 59-61 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al., U.S. Patent 6,316,433, in view of Remington's Pharmaceutical Sciences, and as evidenced by Yamane et al., U.S. patent 4,983,602, in the last Office Action. It was asserted Rose teaches single-dose oral administration of compositions comprising rifalazil in an amount of about 1 mg. An amount of 5 mg is administered in Example 1, column 32. The recitation "about 1" mg of rifalazil reasonably encompasses an amount of 0.8 mg. Motivation to administer a very low dose of rifalazil flows from its documented probability of causing severe adverse reactions and secondary symptoms. See column 4, lines 38-52. Pharmaceutical compositions comprising rifalazil are well established in the art. See Yamane et al., U.S. Patent 4,983,602, column 12, line 58, to column 13, line 10.

Remington provides motivation to prepare a pharmaceutical formulation for oral administration comprising an antibiotic having first and second dosages with a higher amount of active antibiotic in the first dosage unit, as required by instant claim 49. Loading doses are used in many drug regimens when an urgent need exists to achieve a drug steady state. Remington is properly applied as a secondary reference to show a

dosing regimen wherein a higher amount of active antibiotic, i.e., in a loading dose regimen, is dispensed in a first dosage to achieve a therapeutic drug concentration quickly. Such loading doses, as taught by Remington, reflect conventional practice in that the first dose has a higher amount of drug and is followed by a second lower dose, considered to be a maintenance dose.

Applicants argue claims 44-48 can be rejoined because the composition from which these claims depend includes subject matter indicated to be allowable. Applicants state amendments to the claims have been made in a manner consistent with the telephone interview which took place on February 3, 2011. Applicants urge while Rose includes a claim to "about 1 mg to about 100 mg" once or twice a week, the actual administered doses in this dosing regimen were significantly higher than 1 mg.

Applicants state the relevance of the Yamane document is not clear as to how it is applied in the instant rejection. With respect to the rejection of claim 49, Applicants argue the presence of the loading dose and the lower sustained dose are sufficient to overcome the cited references. Applicants state Remington does not discuss the unique problems associated with bacteria that have both a multiplying form and a non-multiplying form. Applicants urge the instant claims provide a therapy that is effective at treating both the multiplying and non-multiplying forms of the bacterial infection.

With respect to claim 53, Applicants argue instructions should be considered as a part of the composition.

Applicants argue the Examiner has already performed a search that would have encompassed methods of treating bacterial infections by administering low doses of rifalazil on a daily basis and the closet art has been identified.

Applicants' arguments, which are substantially drawn to methods of treatment, have been given careful consideration and are persuasive in part. The rejection of claims 1, 2, 4, 5 and 52 is withdrawn. The rejection of claims 49, 53-57 and 59-61 under 35 U.S.C. 103(a) as being unpatentable over Rose et al., U.S. Patent 6,316,433, in view of Remington's Pharmaceutical Sciences, and as evidenced by Yamane et al., U.S. patent 4,983,602, is maintained.

In the telephone interview that took place on February 3, 2011, it was determined only that a claim drawn to the range 0.1-0.25, as supported by Figures 5 and 7, would be given favorable consideration.

Applicants' amendments to the claims have been made in a manner consistent with the telephone interview that took place on February 3, 2011 and relate only to claims 1,2, 4, 5 and 52.

Applicants' suggestion that claims 44-48 can be rejoined because the composition from which these claims depend *includes* subject matter indicated to be allowable is not persuasive. Further search and consideration of the various additional limitations of these claims are required and represent a substantial burden to the Examiner. Rejoinder is not an option at this time.

The claims define the invention. Therefore, even a single recitation of "about 1 mg" in claim 1 is not to be summarily dismissed as irrelevant. One skilled in the art of

formulation chemistry would have reasonably considered a range around the recitation "about 1mg."

The citation in Yamane et al., U.S. Patent 4,983,602, column 12, line 58, to column 13, line 10, was included in the rejection only as evidence that pharmaceutical compositions comprising rifalazil were well established in the prior art.

The unique problems associated with bacteria that have both a multiplying form and a non-multiplying form are not herein at issue. Claim 49 recites "providing instructions for the use of said formulation," and the use is as an antibiotic. However, the instant composition claims do not have any structural differences from the prior art compositions. Therefore, there is no patentable distinction between the claimed invention and the prior art compositions. The pharmaceutical compositions that are suggested by Rose are capable of performing the same antimicrobial use as those instantly claimed. Claims 53-57 and 59-61 are drawn to compositions having instructions for administration. All pharmaceutical preparations that are dispensed to a patient are packaged in pharmaceutical containers along with instructions for administration. The mere placement of instructions within a formulation comprising rifalazil would have been within the general knowledge of one of ordinary skill in the art at the time of the invention. Such a person would have been motivated to do so to promote proper use of the formulation to patients in need thereof and to facilitate patient compliance with a prescribed regimen. Applicants are not entitled to patent a known product by simply attaching a set of instructions to that product. See *In re Ngai*, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004). According to Remington, packaging

of pharmaceutical agents as unit doses, along with instructions thereto, comprising a loading dose, followed by a second, lower dosage unit, is conventional therapeutic practice.

A unit dosage is a finite, discrete drug entity having a specific amount of that drug. Such packaging is entirely conventional. Providing such a formulation in a portable container, or in unit dose packaging, that can be transported to allow for convenient dosing, is conventional.

The determination of optimal doses and dosing regimens is well within the purview of those skilled in the art through no more than routine experimentation. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(II).

Intended use confers no patentable weight to composition claims. A pharmaceutical composition must be both new and unobvious to one skilled in the art. See MPEP 2112 and *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). "Products of identical chemical compositions cannot have mutually exclusive properties." A chemical composition and its properties are inseparable. A pharmaceutical composition must be both new and unobvious to one skilled in the art.

In view of the combined teachings of the prior art, one skilled in the art of formulation chemistry would have been motivated to prepare unit dose packaging of the drug rifalazil in an amount between about 1-5 mg/unit.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Jeff Lundgren, can be reached 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 25, 2011

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1629